FDA's Final Policy on Single-Use Devices (SUDs) Reprocessed by Third Parties and Hospitals

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Objectives

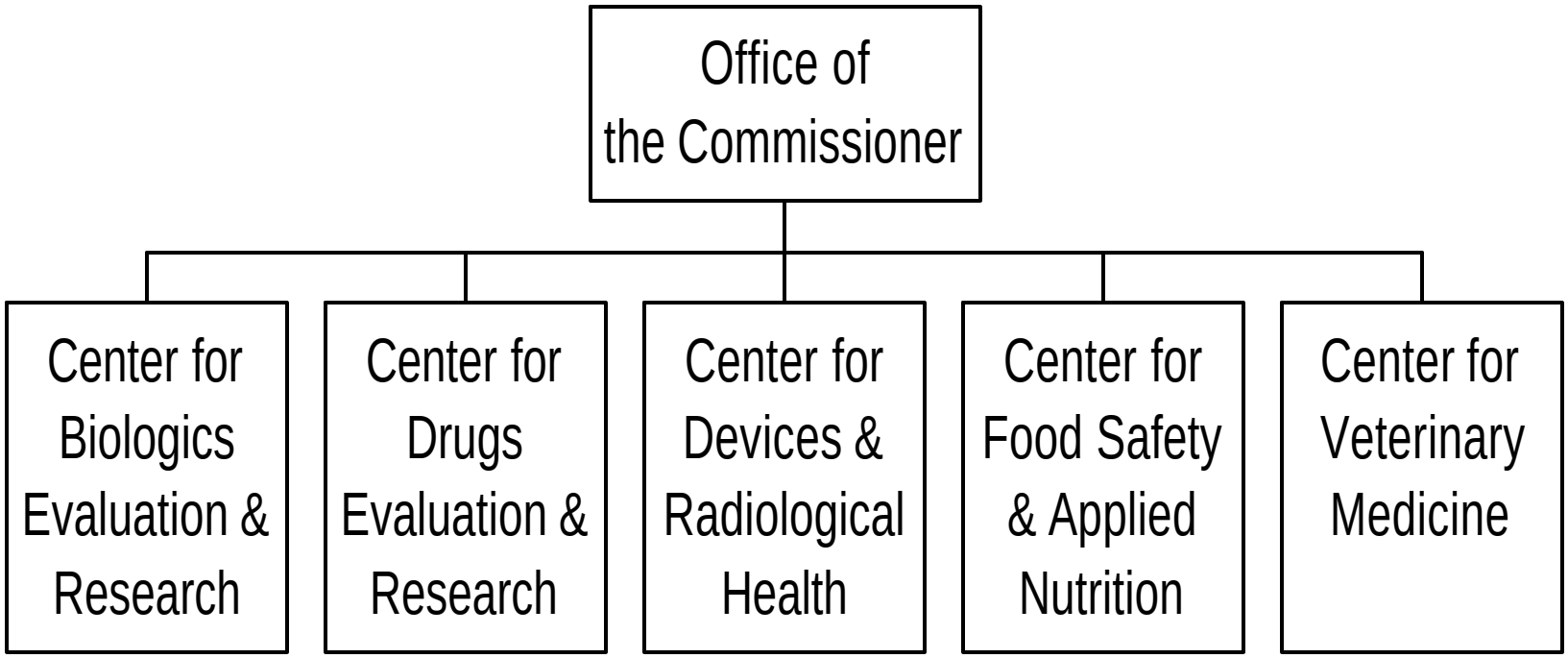
- Background
  - FDA organizational chart
  - CDRH's organizational chart
  - FDA accomplishments
  - Congressional activities
  - Basis of FDA's authority
  - FDA's medical device classification system
  - Types of premarket submissions

Objectives continued

- SUD Enforcement Guidance - Overview
- Opened-but-unused SUDs
- Class I and Class II exempt devices
- Technical concerns
- Vision for the future

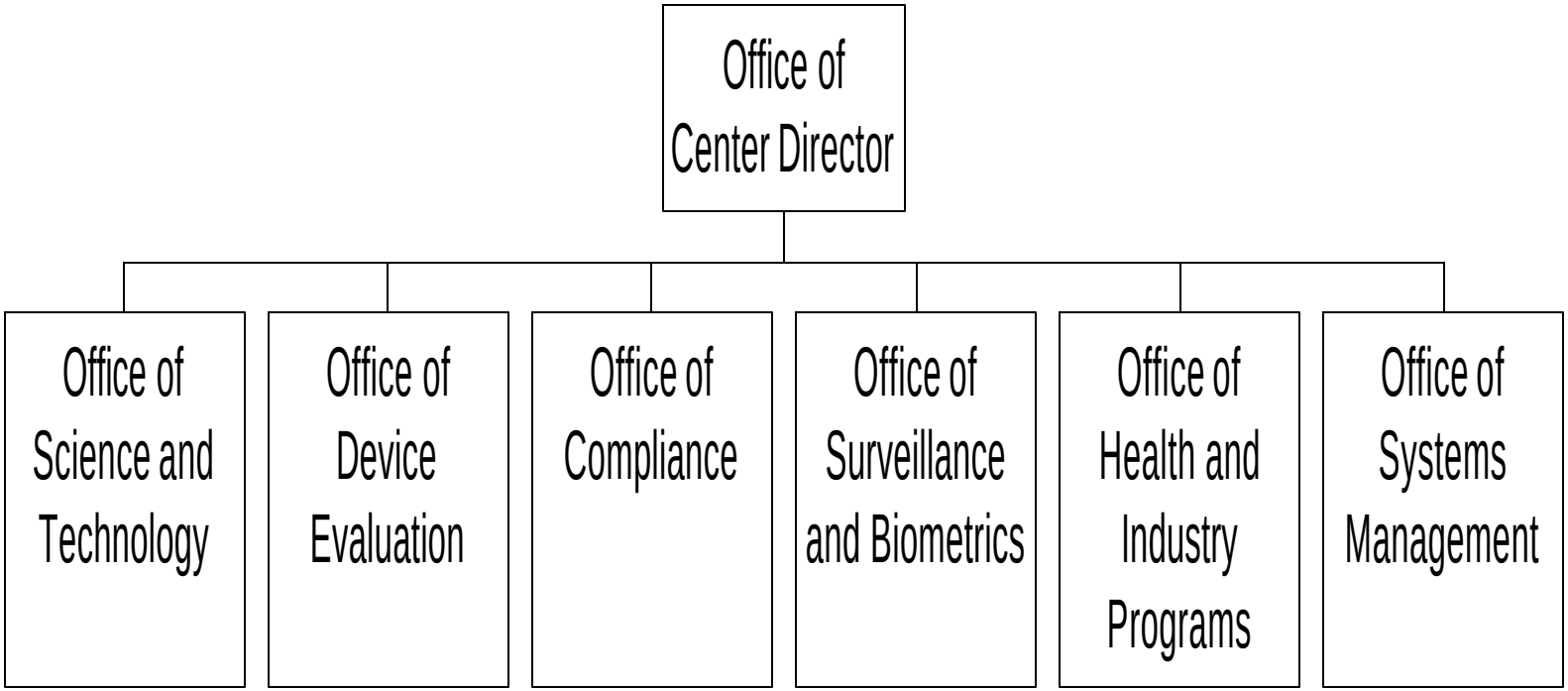
Background

Food and Drug Administration



Background

Center for Devices and Radiological Health



Background

FDA Accomplishments

<u>1999</u>:

Apr 5-6	AAMI/FDA co-sponsors meeting on reuse of SUDs
Nov 3	FDA releases proposed regulatory strategy
Nov 10	FDA sponsors teleconference on proposed strategy
Dec 14	FDA convenes open public meeting to solicit comments on proposed strategy

Background

FDA Accomplishments (cont'd.)

<u>2000</u>:

Feb 11	FDA releases two draft guidances - "*Reprocessing and Reuse of SUDs: Review Prioritization Scheme*" and "*Enforcement Priorities for SUDs Reprocessed by Third Parties and Hospitals*"
Aug 14	FDA issues final SUD Enforcement Guidance

Background

Congressional Activities
106th Congress

- S 1542 "Reprocessed Single-Use Medical Device Patient Safety Amendments of 1999"
  - » Introduced by Senator Durbin (D-IL) on Aug 5, 1999.

- HR 3148 "Reprocessed Single Use Medical Device Patient Safety Act of 1999"
  - » Introduced by Reps. Eschoo (D-CA) and Upton (R-MI) on Oct 26, 1999.

Background

Congressional Activities (con't.)

- Feb 10, 2000

House of Representatives' Committee on Commerce

- Jun 27, 2000

Senate Committee Health, Education, Labor, and Pensions Hearing on the General Accounting Office's (GAO) report "Reprocessing and Reuse of Devices Labeled Single-Use"

Basis of FDA's Authority

- Federal Food, Drug, and Cosmetic Act
- Title 21 Code of Federal Regulations (CFR)
  Parts 800 to 1299

How FDA Classifies Medical Devices

- Class I, Class I exempt
- Class II, Class II exempt
- Class III

Background

Class I

- "General controls" requirements are sufficient to provide reasonable assurance of the safety and effectiveness of the devices

- General controls include:
  - Establishment registration and device listing
  - Adverse event reporting (MDR)
  - Labeling
  - Corrections and Removals
  - Premarket Notifications

Background

Class II

- General controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device

- “Special controls” include:
  - Promulgation of Performance Standards
  - Postmarket Surveillance
  - Patient Registries
  - Specific Guidelines

Background

Class III

- Requires premarket approval in accordance with section 515 of the FD & C Act

- General and Special Controls are insufficient to provide reasonable assurance of the device's safety and effectiveness

Background

Types of Premarket Submissions

- 510(k) = Substantial Equivalence (SE) to a legally marketed device
- PMA = a new device not previously marketed or an existing device seeking a new intended use
- Pre-amendment devices = devices marketed before 1976

“Enforcement Priorities for Single-Use Devices Processed by Third Parities and Hospitals”

August 14, 2000

- www.fda.gov/cdrh/comp/guidance/1168.pdf

SUD Enforcement Guidance:

- Does not apply to:
  - Permanent pacemakers (see CPG 7125.12);
  - Hemodialyzers;
  - Health care facilities that are not hospitals; or
  - Opened-but-unused SUDs.

FDA's Enforcement Guidance

(published in Federal Register on August 14, 2000)

- Registration & Listing (21 CFR Part 807)
- MDR reporting (21 CFR Part 803)
- Medical Device Tracking (21 CFR Part 821)
- Medical Device Corrections & Removals (21 CFR Part 806)
- Quality System Regulation (21 CFR Part 820)
- Labeling requirements (21 CFR Part 801)
- Premarket notification & approval requirements (21 CFR Parts 807 & 814)

1. Registration & Listing

- Owners and operators of establishments who manufacturer devices, including reprocessing of SUDs, must:

- Register their establishment with FDA (FDA form 2891) and
- List each device (FDA form 2892)

2. Medical Device Reporting (MDR)

- Device-related Deaths, Serious Injuries and Malfunctions.
- Report within 30 calendar days after becoming aware of the event.
- Report within 5 work days after becoming aware when event involves a remedial action.
- Submit baseline reports; annual updates as necessary.

3. Medical Device Tracking

- Purpose: to promptly locate devices in commercial distribution in the event corrective action or notification about the device is necessary

- Triggered by a specific FDA Tracking Order to the manufacturer/reprocessor

4. Medical Device Corrections and Removals

- Must submit within 5 work days, a written report to FDA of any corrective or removal of a device that pose a public health risk

  - Correction - the repair, modification, adjustment, relabeling, destruction or inspection of a device including patient monitoring …

  - Removal - moving the device to another location for the purpose of repair, modification, adjustment, relabeling, destruction, or inspection ...

5. Quality System Regulation

- Governs the methods used in, and the facilities and controls used for the design, manufacturer, packaging, labeling, storage, installation, and servicing of all finished devices.

- All hospitals that reprocess SUDs will be subject to periodic FDA inspections

6. Labeling

- General labeling requirements on the device and on all packaging.
- Not limited to just adequate directions for use.

7. Premarket Submission Requirements

- 510(k)

or

- PMA

Significant Dates for All SUD Reprocessors:

- Feb 14, 2001:
  - Submit 510(k)/PMA for all class III SUDs
- Aug 14, 2001:
  - Submit 510(k) for all non-exempt class II SUDs
- Feb 14, 2002:
  - Submit 510(k) for all non-exempt class I SUDs

Special Provision for Hospital Reprocessors

- One year enforcement discretion for non-premarket requirements:
  - registration & listing
  - MDR
  - tracking
  - corrections & removals
  - quality system

“Opened-but-Unused”

“These are devices that are single-use, disposable devices whose sterility has been breached or compromised, or whose sterile package was opened but not used on a patient, that is, they have not been in contact with blood or bodily fluids.“

Class I and Class II Exempt Devices

- Devices that are exempt from premarket submission requirements

HOWEVER …

- They may be subject to GMP/QS requirements!

Some Technical Concerns

- Control of “raw material”
- Defining the specifications
- Identification of changes to OEM devices
- Cleaning and sterilization procedures
- Functionality of a reprocessed SUD
- Bundling of submissions
- Labeling

Vision for the Future

- **Current Reality**

- Widespread practice with little data on safety or effectiveness.
- Single-use labels are not clearly meaningful.
- Ethical concerns.

- **Future Vision**

- FDA approach is risk and science based.
- Horizontal and vertical standards could be useful.
- Leveraging outside parties (e.g., JCAHO)

FDA Home Page on Reuse

- www.fda.gov/cdrh/reuse/index.shtml

FDA Interactive Satellite Teleconference on Reuse of SUDs

Wednesday, December 13, 2000

1:00 to 3:00 PM (EST)

Satellite coordinates: C-Band GE-2, Trans 3 Vertical, Channel 3, Downlink Freq. 3760 MHz, Audio 6.2/6.8

or

contact: http://www.fda.gov/cdrh/ohip/dcm/PROGRAM_CALENDAR/program_calendar.htm